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Quarterly

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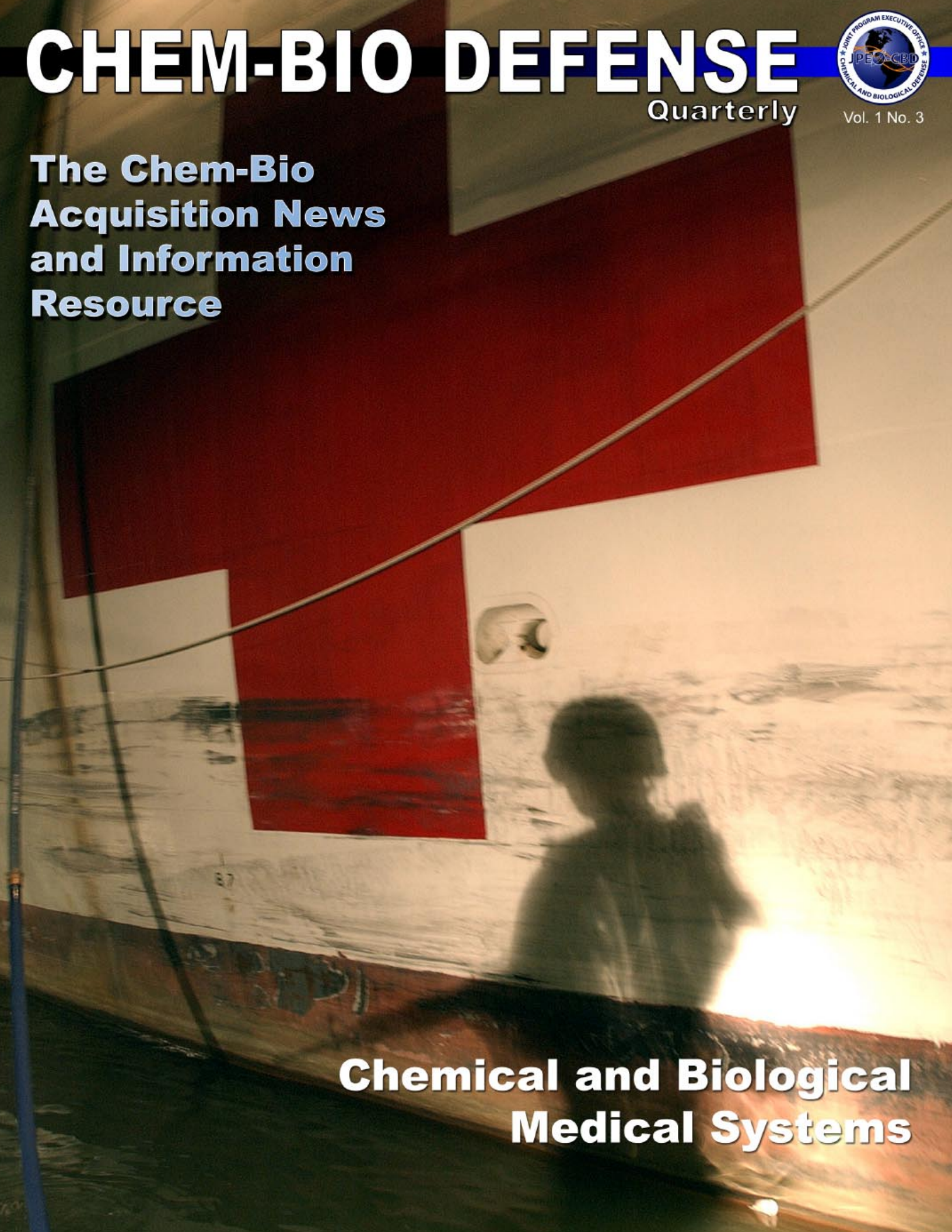
The Chem-Bio Acquisition News and Information Resource



Chemical and Biological Medical Systems

A U.S. Marine from 2nd Fast Company keeps the ship safe during his security watch on the pier alongside the hospital ship USNS Comfort (T-AH 20). Cover photo by Photographer's Mate 2nd Class Aaron Peterson.

Maj. David Shoemaker donned in the Joint Service Lightweight Integrated Suit Technology demonstrates the proper technique for administering the Antidote Treatment Nerve Agent Auto-injector.

Col. Don Burnett
USA

Col. Camille Nichols
USA

Mr. Doug Bryce
USMC

Capt. Tom O'Keefe
USN

Col. Stephen Berté
USA

Col. Albert Burnett
USAF

Mr. Stan Enatsky
USN

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Photo by Steven Lusher

From the Joint Program Executive Officer

Brigadier General Stephen V. Reeves
Joint Program Executive Officer
for Chemical and Biological Defense

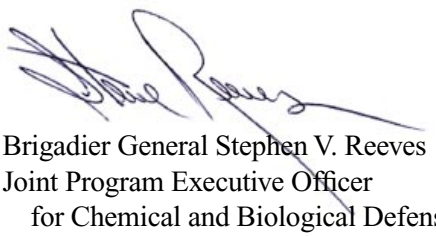
Three years ago, the daily threat from Anthrax primarily concerned cattlemen, sheepherders, and veterinarians. Today, because of letters containing Anthrax, and the Global War on Terrorism, practically everyone has some knowledge of Anthrax as well as other chemical and biological threats.

Yet for the Department of Defense (DoD), these threats are not new. For more than 200 years, U.S. military medicine has addressed battlefield medical threats. With the first large scale use of chemical agents during World War I, the need for specialized treatments for chemical threats was recognized. Since then, DoD's medical research and development organizations have substantially matured with an established infrastructure of laboratories and highly trained research and acquisition personnel. They consistently demonstrated the capability for solid technology developments, experimentation with new agents to preclude technological surprise, and fielding medical products and countermeasures on large scales.

In this issue, we introduce some of the people who are leading the chemical and biological defense effort in the advanced development of products for our warfighters. Since establishing the Chemical and Biological Medical Systems Program Office in 1997, 11 new chemical and biological defense countermeasures have been fielded or are in clinical trials. These products are, in many cases, the culmination of many years of work in the technology base. We also discuss the U.S. Food and Drug Administration's (FDA) vital role in ensuring our medical products are safe and effective.

As we look to the future, we are coordinating with, and leveraging the efforts of other Government agencies, such as the Department of Homeland Security and the Department of Health and Human Services, ensuring we jointly deliver FDA approved products as rapidly as possible.

Finally, this month we welcome Dr. Klaus Schafer, MD, as the new Deputy Assistant to the Secretary of Defense for Chemical and Biological Defense. Dr. Schafer brings a wealth of military and medical knowledge and experience to the Joint Services Chemical and Biological Defense Program and we look forward to his leadership and working with him.



Brigadier General Stephen V. Reeves
Joint Program Executive Officer
for Chemical and Biological Defense

Joint Program Executive Office

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The Transition of Individual Protection

By William Hartzell, Danielle Fleming, and Peter Hernandez

A year ago, Individual Protection (IP) was officially adopted into the Joint Chemical Biological family. Some aspects of the transition were challenging but these "opportunities" were managed well and IP continued to provide outstanding support to the Joint Service Warfighter.

The IP Program provides cradle-to-grave support for over a dozen legacy and developmental programs designed to protect the warfighter against chemical, biological, radiological and nuclear threats. The legacy Joint Service Lightweight Integrated Suit Technology (JSLIST) ensembles continue to be fielded. Our combat forces used JSLIST extensively in Afghanistan and Iraq and reports from the field are that the suits fit comfortably and perform well. Lessons learned will be used for additional improvements to suits, boots, gloves and masks. Also, the IP Team is working hard to develop and field joint service, state-of-the-art protective masks for our ground troops and airmen. Items currently in development are a throw away survivability mask, a general purpose mask for ground troops, an aircrew mask for use on all aircraft platforms, and a portable tester troubleshoots defects and to verify the mask is fitted and works properly.

In between working the day-to-day requirements for developing and fielding equipment to the warfighter, we have responded to numerous requests for informational material. The IP team has also supported conferences, symposia and homeland defense initiatives and we are currently working a project to improve IP asset management, via the Joint Total Asset Visibility Reporting Warehouse (JTAVRW) initiative.

Bottom line, it has been a very challenging and successful first year and the reason for our success is our people; we have a great team in place here at Quantico and at the various IP program sites. Working hand in hand with the JPEO and his staff, we plan to accomplish even next year!

Delivering Medical Countermeasures to the Warfighter

By Col. Stephen Berté
Joint Project Manager CBMS

Chemical Biological Medical Systems (CBMS) is the Joint Project Management Office (JPMO) responsible for the advanced development of U.S. Food and Drug Administration (FDA) approved medical countermeasures against chemical and biological warfare agents for the DoD. It was born in April 2003 as a result of a congressionally mandated reorganization of the Department of Defense Chemical and Biological Defense Program (CBDP) described in the Chemical and Biological Defense Implementation Plan (CBDIP). The intent of the CBDIP was to bring all CBDP development, including medical items, under the direction of a single office, the Joint Program Executive Office for Chemical

Photo by Steven Lusher

Biological Defense (JPEO-CBD). CBMS is one of seven JPMOs reporting to the JPEO-CBD.

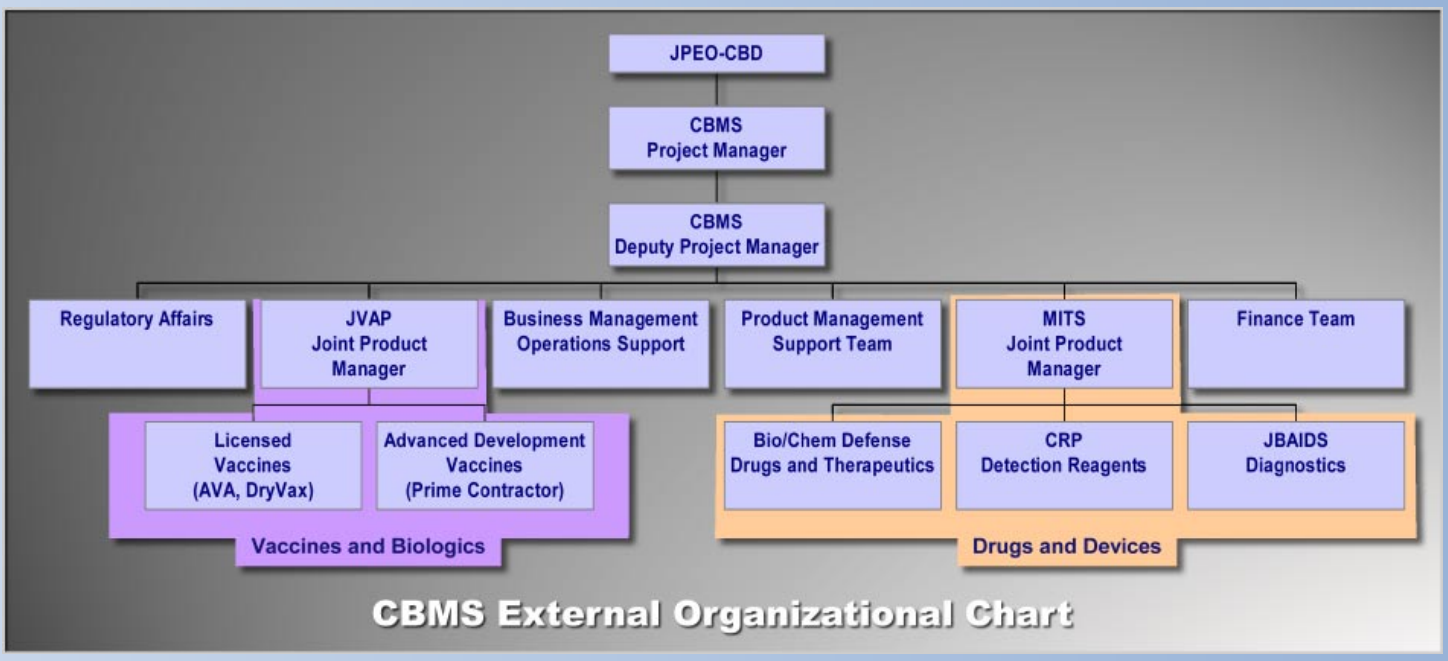
CBMS is comprised of two subordinate commands, the Joint Vaccine Acquisition Program (JVAP) and the Medical Identification and Treatment Systems (MITS) Product Management Offices. JVAP was initially organized in 1997 as a stand-alone program responsible for the development of vaccine systems. Its mission focus, that of developing vaccines to protect DoD personnel from the effects of Biological Warfare Agents (BWAs), remains unchanged under CBMS. The newly formed MITS incorporates three developmental efforts that were formerly part of the U.S. Army Medical Research and Materiel Command (USAMRMC) and the predecessor to the JPEO-CBD, the Joint Program Office for Biological Defense. The MITS programs include the development of pharmaceutical countermeasures to chemical and biological warfare agents, the Joint Biological Agent Identification and Diagnostic System (JBAIDS), and the Critical Reagents Program (CRP). The pharmaceutical development program has resulted in such FDA approved products as pyridostigmine bromide Soman nerve agent pretreatment tablets, skin decontamination kits, and the various autoinjectors carried by DoD forces. The JBAIDS is a new program focused on developing an FDA licensed system for diagnosing the presence of BWAs in patients. Medical diagnostic devices take detection a step further. Detection uses scientific procedures to identify the presence of biological or chemical warfare agents in air, water, soil, on a surface, etc. Diagnostic devices subject the process to approval by the FDA as a diagnostic tool, i.e., allowing physicians to use the tool to analyze patient specimens and prescribe medical treatments based on the outcome of the tests. This in part explains why the CRP program is in CBMS as it develops and provides reagents needed to make the various DoD detectors and the JBAIDS work.

The process for developing vaccines and drugs is a process driven by FDA regulations that ensure the safety and effectiveness of medical products for the nation. A critical and unique component of the CBMS mission is therefore the integration of the DoD acquisition and FDA regulatory processes. The flexibility of the DoD acquisition program has made it possible for CBMS to meet both DoD and FDA requirements without adversely affecting product development cost, schedule, or performance. CBMS is focused on meeting industry standard development times which are in the range of seven - 10 years for the advanced development portion of the process. This is due in part to the complex and phased animal and human testing requirements associated with medical product development and the fact that each vaccine or drug presents unique developmental and manufacturing challenges. Despite these challenges, CBMS is not satisfied with only meeting industry standard metrics, but is determined to continue to explore ways to shorten our development schedules while still providing premier medical capabilities to the warfighter.

FDA regulations ensure the safety and effectiveness of medical products. However, until recently, it was virtually impossible to obtain FDA licensure of Chemical Biological Warfare Agents (CBWA) countermeasures because product efficacy could not be demonstrated in humans since it is unethical to expose human subjects to CBWAs. The few countermeasures that were licensed (e.g., vaccines such as smallpox and anthrax), achieved licensure because the diseases they protect against also occur in humans as natural infectious diseases. This enabled tests to be done to measure the products' effectiveness in areas where the diseases were found. In 2002, the FDA established the so-called "animal rule" which provides a means for testing product efficacy in animals and demonstrating that the results in animals are relevant to humans. DoD was the first to take advantage of the animal rule when it achieved FDA approval of pyridostigmine bromide tablets.

CBMS has realigned its acquisition strategy to fully fund the highest priority DoD needs within available resources, in industry standard time, and is leveraging national and international partners to get capabilities to the warfighter. The new strategy addresses user requirements based on the Chairman of the Joint Chiefs of Staff priorities and produces FDA licensed products.

We are applying funding to achieve licensure on schedules commensurate with industry standards. As an example, the



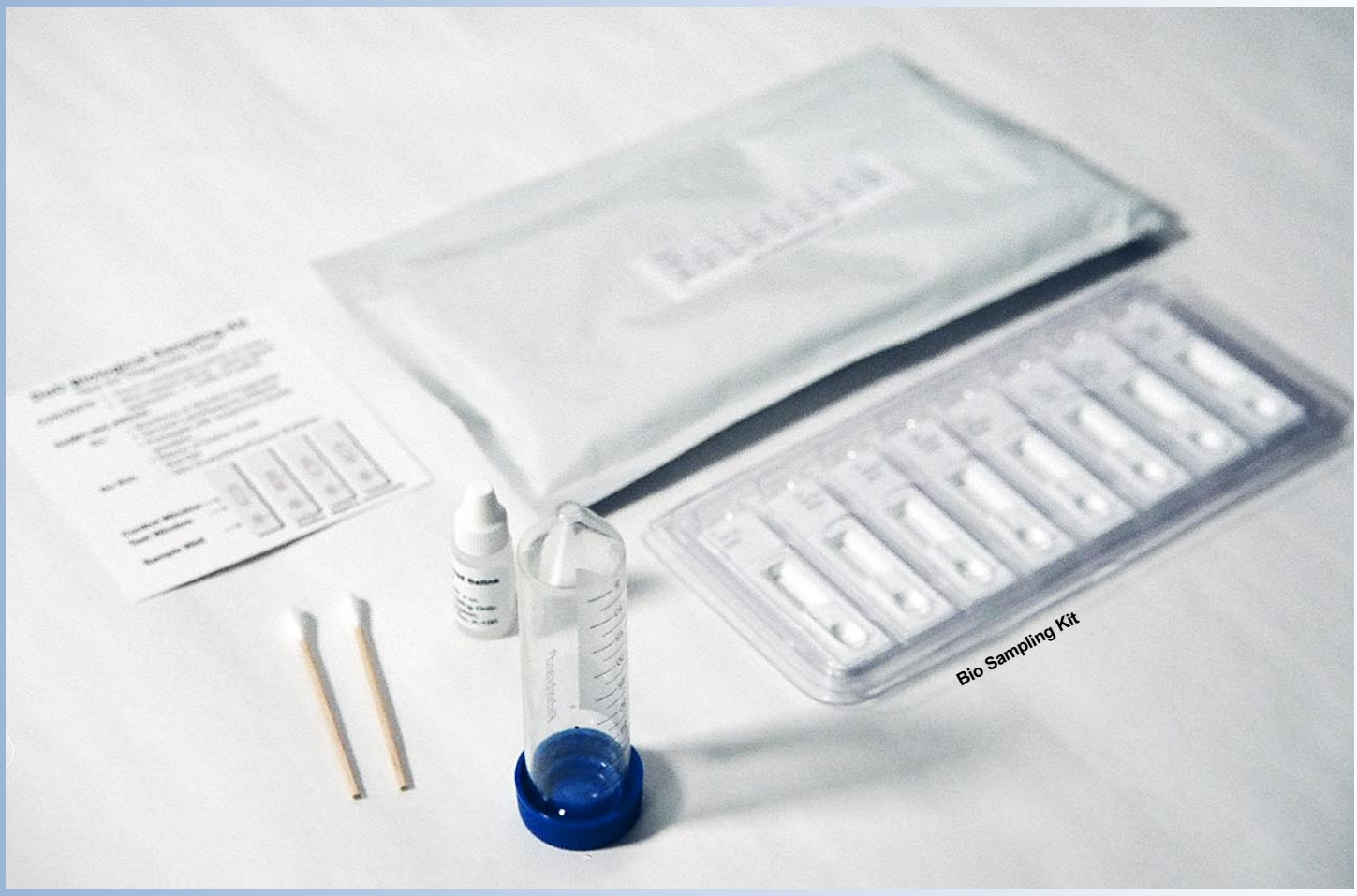


Photo by Elizabeth Sass

JVAP became fully operational in 1998. Industry standards would project a product could be ready by 2005-6. In fact, Vaccinia Immune Globulin - Intravenous (used to treat adverse reactions to smallpox vaccines), is on schedule for licensure in 2005-6. Our strategy and budget are now aligned to ensure we achieve similar success with other products.

CBMS manages our product line within available resources by putting sufficient funding on a program to achieve industry standard schedules then expanding or contracting our product line based on available funding. In the past, a focus on developing as many products as possible resulted in funding being spread across many programs leading to longer development times. We are seeking funding through the Enhanced Planning Process and FY06 - FY11 Program Objective Memorandum (POM) build to fund products the technical base projects will be ready for transition during the POM. International partnerships achieved through Project Arrangements (PAs) under provisions of the Canadian/United Kingdom/United States Chemical, Biological and Radiological Memorandum of Understanding allow CBMS to leverage our allies to achieve combined success in developing medical products licensed in all three countries. CBMS has a PA with Canada for smallpox vaccine system and a PA with UK and Canada is being staffed so support a cooperative effort on development of a Plague vaccine. The UK and Canada have expressed interest in collaborating on other current and future CBMS products.

CBMS is also leveraging U.S. Department of Health and Human Services (DHHS) efforts that are focused on FDA licensure and meeting warfighter requirements. Civilian requirements often emphasize treatment more than prophylaxis which is DoD's higher priority. CBMS must ensure that any collaboration that involves shifting of a DoD priority program to DHHS will result in a licensed product for DoD use. Current analysis of DoD and DHHS programs is that there are no significant gaps, some overlap, and some complementary programs.

Project Bioshield offers another opportunity for CBMS to leverage non-DoD resources. Bioshield funding can be used to meet DoD requirements when there is commonality with national requirements. CBMS is working to identify products that can use Bioshield funding and is currently working cooperatively with DHHS on a project that will likely result in use of these funds.

A key player in any advanced development program is the technology base that discovers and initially develops product candidates for advanced development. CBMS is fortunate to be part of a truly outstanding team focused on developing medical products to meet DoD prioritized needs. The research laboratory system of the USAMRMC provides world-class support that produce a wealth of candidates for chemical and biological warfare agent countermeasures.

CBMS has a diverse product line being developed by a superb team of military and government civilians and contract personnel plus outstanding contractors. Other related articles in this edition will give you a better understanding of the unique nature of our mission of delivering premier FDA licensed medical countermeasure capabilities to the warfighter at the right place, at the right time for the right price.

Developing Medical Products for the Department of Defense

By Lt. Col. (Ret.) Harold E. Modrow

Developing and fielding medical products to protect warfighters from the effects of either chemical or biological warfare agents presents unique challenges to the Acquisition Professional. However, recent revisions to DoDD 5000 have given the Acquisition Professionals at the Chemical Biological Medical Systems (CBMS) Joint Project Management Office an opportunity to tailor the acquisition process and develop these lifesavings products.

U.S. Department of Defense policy (DoDD 6200.2 and Executive Order 13139) states that in most foreseeable situations, military personnel will receive only medical products approved by the U.S. Food and Drug Administration (FDA). For this reason, FDA approval is obtained for all medical products, including drugs, vaccines, and medical devices, prior to full rate production and fielding for use by warfighters. This means that the FDA regulatory and approval process must be incorporated into the normal DoD Acquisition Strategy. The FDA requires that the developer must demonstrate that the product (either drug or vaccine) is both safe and effective against the disease or indication for which approval is requested. While it is relatively easy to prove product safety, proving effectiveness of protection against chemical or biological warfare agents is extremely challenging. Obviously, it is unethical to test a product in humans by exposing them to either chemical or biological agents. For that reason, the pivotal research to demonstrate that the product will indeed protect against such agents was until recently nearly impossible. However, the FDA has recognized this problem and published what is known as the "animal rule." As a result of this rule, it is now possible to gain FDA licensure of medical products to protect our forces from chemical and biological warfare agents. Unfortunately, testing necessary to use the animal rule is not necessarily faster or less expensive than the conventional approval process. It requires extensive knowledge of the disease or toxic process as it is displayed in each animal species as well as the nature of the protective effect of the drug or vaccine in that species.

The acquisition process for drugs and vaccines is very similar to that of other military materiel. The Joint Requirements Office (JRO) identifies a requirement or capability gap through an Initial Capability Document. In the technology base, researchers will identify a potential solution to meet the gap. Prior to a Milestone A, the technology base is expected to conduct proof of concept research. This usually includes initial safety and efficacy studies in animals and an initial evaluation of the feasibility/ease of formulating the drug or vaccine, which is dependent on the physical and chemical properties of the drug or vaccine. After a Milestone A, an additional series of studies must be conducted in animals. During these studies, a surrogate clinical end point (that is, a measure of effectiveness in humans and in animals) in an animal model is further defined. Additionally, a series of studies must be conducted in animals to evaluate the toxicology of the product and determine how the drug or vaccine is distributed throughout the body. Concurrent with such studies, the manufacturing process must be developed.

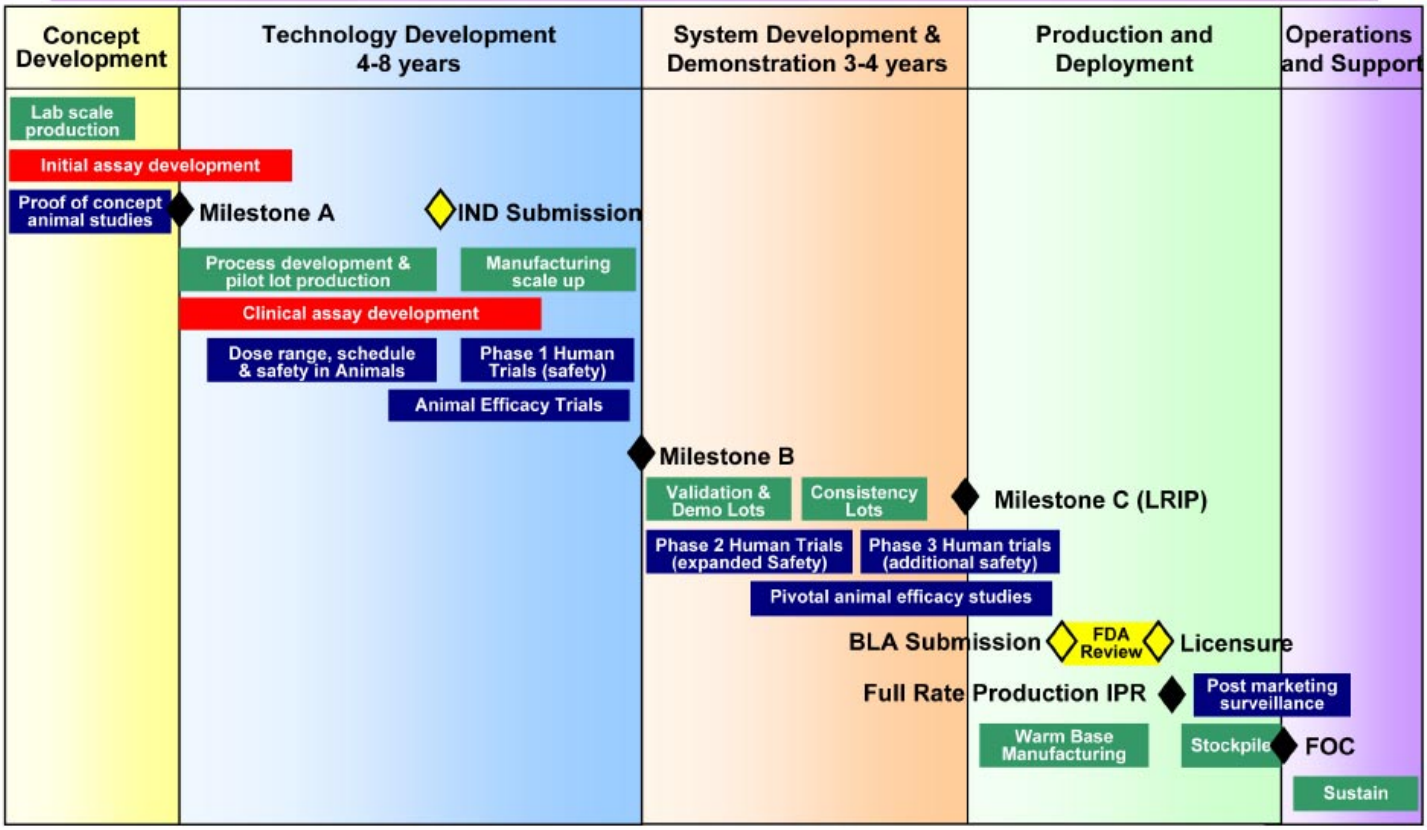
When sufficient data have been collected in animals, a meeting is held with the FDA to discuss the results from the animal and manufacturing process efforts. After the meeting, an Investigational New Drug (IND) Application is prepared and submitted. This application must lay out essentially everything known about the proposed vaccine or drug to include all animal data, the manufacturing process and most importantly the protocol for the first proposed use in humans. The first human study is a small study usually consisting of 15 to 25 volunteers to ensure the drug or vaccine is safe. This study and all clinical research involving humans must be conducted under extremely rigorous standards. After the human clinical protocol is prepared describing exactly how the study will be conducted, it must be reviewed and approved by at least two different scientific and human subject research review boards prior to submission to the FDA. The FDA then has at least 30 days to review the IND and the protocol. Only after all approvals are received can the study actually be conducted. All human research that may assist in obtaining final drug or vaccine approval from the FDA must be conducted under strict FDA regulations and guidelines commonly referred to as "Good Clinical Practices". This means that the entire research effort must be completely documented and any change or variation must be written down and submitted to an oversight board. At the completion of the initial human safety studies and additional animal studies, if there is still a requirement and if the proposed solution product still appears promising, a product package is prepared for a Milestone B IPR.

After a successful Milestone B, the

Photo by Elizabeth Sass

Military personnel will receive only medical products approved by the U.S. Food and Drug Administration (FDA).

Integration of FDA Regulatory Process and DoD Acquisition Model for Vaccines



product will continue through the clinical development process (See associated article in this issue on Human Testing). During this time, validation and demonstration lots of the compound are manufactured in the expected final formulation and dosage. The actual manufacturing process must be approved by the FDA to include documentation of every aspect of manufacturing and the source of all raw materials. Multiple lots must be manufactured and tested to ensure the consistency of the manufacturing process and every dose in every lot. A significant difference in the development of drugs and vaccines is in the manufacturing process. In the case of drugs, often the small manufacturing process utilized in early development can be geared up for large scale with few changes. The FDA will be satisfied with a demonstration that the process works. For this reason the increase in manufacturing capacity will occur late in the drug development process, often after the actual FDA approval. On the other hand, changes in the vaccine manufacturing process after trials have begun may negate the previously completed trials and require having to repeat some clinical trials with the new product formulation. This means that the vaccine manufacturing process must be geared up for large lot size earlier in the development cycle simply to demonstrate feasibility and consistency of the manufactured lots.

Because vaccines are not carried or utilized by individual soldiers, they do not require a Test and Evaluation Master Plan (TEMP). The DoD has recognized that the FDA approval process is extremely rigorous in ensuring product safety and efficacy. However self-administered drugs, e.g., nerve agent or other chemical warfare treatments, do require a TEMP to ensure the packaging is durable and the instructions are clear so the product is administered as directed.

During the post-Milestone B period, additional human studies utilizing larger and potentially more diverse populations must be conducted to ensure the product does not have serious adverse effects in warfighters. The definitive animal efficacy studies are usually conducted in at least two different species, one of which is a non-human primate, to make sure the drug or vaccine, as manufactured, will work. The FDA closely examines these large studies. When all research and manufacturing efforts are completed, the Milestone C package is prepared and submitted for approval. After approval, a New Drug or Biological License Application is prepared and submitted to the FDA. If the FDA approves the product, a full rate production In Process Review is held.

The mission of the Acquisition Professionals within the CBMS Project Management Office is to develop and field lifesavings products for the warfighters. Using the flexibility of DoD 5000, the CBMS PMO has merged the DoD acquisition and the FDA regulatory systems into a unique process to develop, test and obtain FDA licensure for products to prevent, protect against, and treat the lethal effects of chemical and biological warfare agents.

Related article: Animal Rule

Protecting the Warfighter: Use of FDA's Animal Rule for Efficacy

By Michelle Mathers, Regulatory Affairs Analyst, Camber Corporation

The development of biological warfare defense vaccines and other defense agents present unique challenges for demonstration of safety and efficacy. Human efficacy trials are not feasible or ethical when drugs or biologics are being developed to reduce or prevent serious or life-threatening results of exposure to biological agents or toxic chemical, radiological, or nuclear substances. As a result, the U.S. Food and Drug Administration (FDA) proposed the Animal Efficacy Rule, or "animal rule" to obtain efficacy data by use of animal models of efficacy. The final rule became effective June 30, 2002 and was added to the Federal Register for drugs and for biologics such as vaccines. This amendment allows the use of well controlled animal studies to determine that the product is likely to provide clinical benefit in humans.

Photo by Elizabeth Sass

The first medical countermeasure to be approved by the FDA using the animal rule was the U.S. Army's pyridostigmine bromide (PB) in February 2003, for an indication to increase survival after exposure to Soman nerve agent poisoning.

The animal rule applies to those products for which definitive human efficacy studies cannot be conducted because it would be unethical to deliberately expose healthy human volunteers to a lethal or possibly disabling substance and where field trials to study a product's effectiveness after an accidental or hostile exposure are not feasible. It does not apply to products that can be approved based on efficacy standards described elsewhere in the FDA's regulations. The product must be expected to provide a greater benefit than prior existing therapies, if they exist. The mechanism of action of the article tested as well as the threat agent must also be well understood. The pivotal data must be scientifically appropriate and tested in multiple species, including at least one that will give a response predictive to that which is expected in humans. The animal rule does not address product safety. Safety must be established in human clinical trials. However, the FDA recognizes that data for interactions between the new product and the toxic agent that it is protecting against will not be available. The results of both animal and human data are used to select an effective dose in humans.

The first medical countermeasure to be approved by the FDA using the animal rule was the U.S. Army's pyridostigmine bromide (PB) in February 2003, for an indication to increase survival after exposure to Soman nerve agent poisoning. This agent causes loss of muscle control and death from respiratory failure. The product was approved for combat use by U.S. military personnel. However, because there was no way prior to institution of the animal rule to get FDA approval for products used against chemical and biological warfare agents, PB could only be used under the FDA's Investigational New Drug (IND) provisions during the first Gulf War based on safety data from long-term use of PB, it was first approved by the FDA in 1955 to treat the neuromuscular disease, myasthenia gravis and the dose used for that condition is higher than the dose used for pretreatment to protect against Soman. Evidence of the effectiveness of PB as a pretreatment for exposure to Soman was obtained primarily from studies in rhesus monkeys and guinea pigs. It was shown that administration of the drug before exposure to Soman, together with atropine and pralidoxime given after exposure, increases survival in animals. Thus, research was able to show that PB bound to and protected an enzyme in an animal model which in turn enhanced survival in the animal from exposure to a chemical warfare agent; this binding to the same enzyme then had to be demonstrated in humans. The FDA therefore believes that, based on the animal evidence of effectiveness, pyridostigmine bromide is likely to benefit humans exposed to Soman.

With increasing demand for new vaccines, we are fortunate that through the Animal Rule amendment, the FDA can now approve products which otherwise would not have efficacy data to support their approval. The DoD and our nation are fortunate to have this new tool in our arsenal for getting chemical and biological warfare agent countermeasures approved for the warfighter.

CBMS Integrated Medical Products

By Lt. Col. (Ret.) Harold E. Modrow

The mission of the Chemical Biological Medical Systems (CBMS) Joint Project Management Office (JPMO) is to develop, procure, field, and sustain U.S. Food and Drug Administration (FDA) licensed medical protection, diagnostic, and treatment capabilities against chemical and biological warfare agents. The work of this office stretches across the entire spectrum of chemical / biological defense from prophylaxis prior to exposure to long-term post-exposure treatment. Preventive measures, or prophylaxes, (e.g., vaccination or pyridostigmine tablets) preserves the force and may negate the threat of attack in the protected troops. Treatment with drugs after exposure to chemical or biological agents preserves warfighters' lives.

Vaccines act by fooling our immune system into believing it has been exposed to a given disease. They do this by using an altered form or portion of the causative agent of the diseases (e.g., virus, bacterium, etc.) that will not cause disease but will cause an immune response in the vaccinated person. If a person is exposed to the biological agent in the future, their body's immune system is primed and ready to fight off the infection or toxin it encounters. It is a fact that vaccines, whether to biological warfare agents or infectious disease (e.g., mumps, influenza, etc.), do not provide protection to 100 percent of the force. Depending on many factors, anywhere from five percent to 30 percent of those receiving vaccinations will not develop sufficient immunity after the vaccination or series of vaccinations. Additionally, there may not be time between the vaccination and the actual agent exposure to build up the necessary immunity for adequate protection. For these and other reasons, we will always need physical protection and drugs to provide added protection and treatment for those who become ill after exposure. Vaccines can be developed against viruses and bacteria but not chemicals. Drugs and other biological compounds are needed to treat those exposed to chemical warfare agents.

Development and fielding of medical products requires that an entire medical system be produced, including the actual drug or vaccine as well as a dedicated production facility and the logistics and training packages associated with the product. Although the process for medical product development is similar between CBMS and pharmaceutical companies, selection of products to be developed and timelines for development vary markedly. First and foremost, pharmaceutical companies must always operate for a profit. If a drug or vaccine does not have a potential to make a profit for a company, it will not likely be developed irrespective of the need for the product. On the other hand, although cost is an important factor to consider in development, DoD drug and vaccine development must satisfy operational requirements and comply with the President's budget. If there is not an operational requirement, there will be no program. Timelines and product development costs also differ between CBMS and pharmaceutical companies. Industrial standards are approximately seven to 12 years and $500 to $800 million for the development of a single drug/vaccine from technology base to FDA licensure. The cost is such because many products that are initiated in development never actually reach licensure. The typical pharmaceutical company will focus most of their assets on a limited number of products and try to get them to market as quickly a possible. They accept the risk that a percentage of these products will not succeed and so fund multiple candidates for longer periods of time than can DoD. CBMS ensures timely delivery of products to meet warfighter requirements by limiting the number of products developed at any one time based on available funding. All decisions on initiation and termination of products take priority of requirements, available resources, and the stage of product development into consideration. This approach results in projected CBMS product development schedules being in line with industry standards.

The CBMS JPMO has two subordinate Joint Product Management offices; the Joint Vaccine Acquisition Program (JVAP) and the Medical Identification and Treatment Systems (MITS). Each of these offices has a number of medical

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products under development and currently fielded.

The JVAP is responsible for the development and fielding of all vaccine systems to protect the warfighter from biological warfare agents. This includes management of the production of Anthrax Vaccine Adsorbed (AVA) and vaccine candidates against Botulism, Plague, and Venezuelan Equine Encephalitis (VEE) as well as Vaccinia Immune Globulin - Intravenous (VIGIV), an immune globulin to treat patients who have negative reactions to the smallpox vaccine. The JVAP is leveraging other government agencies' efforts and so is monitoring the results of a Department of Health and Human Services (DHHS) sponsored smallpox vaccine development program which should provide a smallpox vaccine that DoD could purchase.

The JVAP is responsible for the development and fielding of all vaccine systems to protect the warfighter from biological warfare agents.

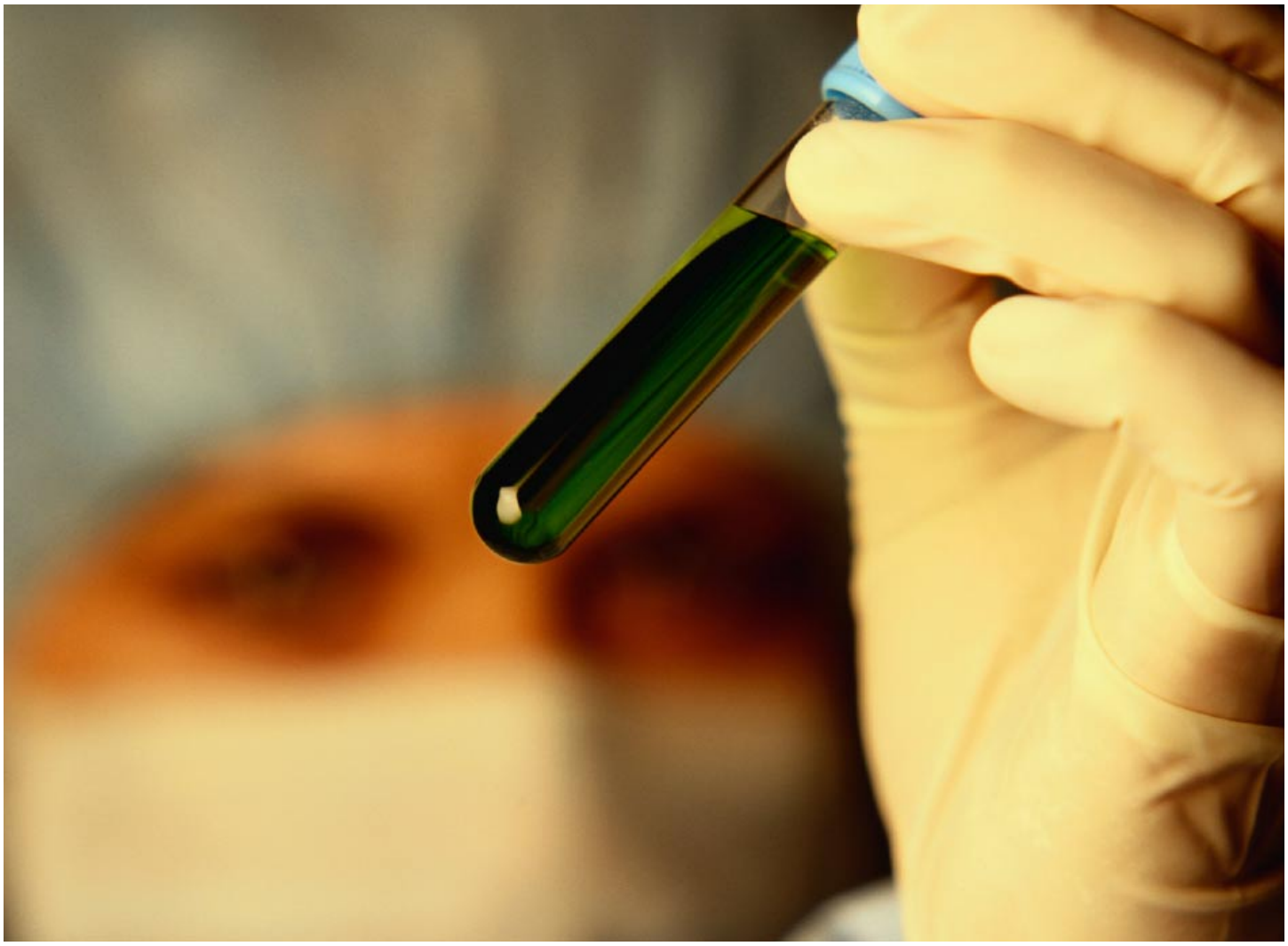
The MITS currently develops and fields drugs and biological compounds for the treatment of chemical agent exposure. They are also responsible for the development of devices for the diagnosis of patients exposed to biological and infectious disease agents. The Joint Biological Agent Identification and Diagnostic System (JBAIDS) is a new integrated system intended for the rapid identification and diagnostic confirmation of biological agent exposure or infection. This is the first DoD effort for the development of a common identification and FDA approved diagnostics platform. The product passed Milestone B in September 2003. The first six assays for biological agents should be available for the Low Rate Initial Production In Process Review in late 2004. When ultimately completed using a spiral development approach, assays will be available for as many as 15 different biological disease agents and toxins.

The MITS also has a number of products either under development or expected to transition to advanced development within the next year or two. The Advanced Anticonvulsant System (AAS) is intended to replace the current Convulsant Antidote Nerve Agent (CANA). The AAS will be more effective in stopping the generalized convulsions associated with nerve agent poisoning. This effort will require both animal and human research studies to adequately demonstrate the effectiveness of the AAS in controlling seizures. Final FDA licensure is expected in FY12. The Improved Nerve Agent Treatment System (INATS) is intended to replace the current oxime, 2 PAM chloride in the recently fielded Antidote Treatment Nerve Agent Autoinjector (ATNAA). The goal of this program is to select a new oxime that will provide a greater effectiveness against both traditional and non-traditional nerve agents. Fielding of this oxime may not occur until FY15 due to the large numbers of research studies necessary to demonstrate efficacy against multiple nerve agents and safety in humans. As a part of this effort, the MITS will conduct studies to show that pyridostigmine will enhance the effectiveness of the new oxime. In addition, bioscavenger products are advancing toward advanced development. These products contain an enzyme occurring naturally in humans that works in a manner identical to the Cholinesterase already in the blood stream. The products contain higher levels of the enzyme and so provide more protection than our own blood levels of the enzyme can. Bioscavengers therefore can inactivate nerve agents before they would have a chance to produce convulsions and other symptoms in the service member. Current concepts propose that a single injection of this product may protect a warfighter for as much as two weeks after the injection and is intended to be used with protective ensembles, not in place of them.

The MITS also has lifecycle oversight for a number of products already FDA licensed and fielded to the military. These include the ATNAA, commonly called the multi-chamber autoinjector, Soman Nerve Agent Pretreatment Pyridostigmine (SNAPP), and Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA).

ATNAA replaces the Mark I Autoinjector. It consists of a single autoinjector containing both atropine and 2-PAM oxime for the treatment of nerve agent exposure. This new autoinjector is less expensive than the Mark I and also requires less space. The FDA has approved a shelf life of three years for this product at this time. It is anticipated that it will be given a five-year shelf life approval when the appropriate tests are complete. Pyridostigmine (SNAPP) as a pretreatment drug to improve survival chances after exposure to Soman. SERPACWA is a skin barrier cream used in conjunction with Mission Oriented Protective Posture (MOPP) gear to enhance individual protection against chemical warfare agents. Applied to the skin in those areas where the agent might get through the MOPP, either because of an improper closure or because of sweat-through (neck, wrist, ankles, waist, armpit, and groin), this product increases protection afforded by the MOPP.

The CBMS program seeks to conserve the fighting strength of the forces through prevention and treatment of human death and illness caused by biological and chemical warfare agents. If either chemical or biological warfare agents are used against Americans, products developed by the CBMS team will protect them from illness or death, rapidly diagnose and then treat those that do become casualties to return them to their units.



Producing Drugs and Devices for the Warfighter

By Lt. Col. Edward T. Clayson, Ph.D., JPM MITS

The Medical Identification and Treatment Systems (MITS) - Joint Product Management Office (JPMO) was stood up on June 1, 2003 with the mission to develop, stockpile and field drugs and devices to protect warfighters from chemical and biological warfare agents. Three separate and distinct programs were pulled together to form the MITS-JPMO: The medical chemical defense advanced development program which was formerly managed by the U.S. Army Medical Materiel Development Activity (USAMMDA) of the U.S. Army Medical Research and Materiel Command (USAMRMC); The Joint Biological Agent Identification and Diagnostics Systems Program formerly managed by the Joint Program Office for Biological Defense (JPOBD); and The Critical Reagents Program, also formerly managed by JPOBD.

The Department of Defense has requirements for drugs that prevent or treat illness from exposure to chemical or biological agents as well as nuclear radiation. DoD policy (DoDD 6200.2 and Executive Order 13139) calls for these drugs to be approved by the U.S. Food and Drug Administration (FDA). Several antibiotics, such as ciprofloxacin, doxycycline and penicillin are approved by the FDA as treatments against several bacterial biological agents. These antibiotics are currently in the medical logistics system and are available for use. Therefore, the MITS-JPMO does not invest limited development funding for the development of new antibiotics. Antiviral drugs are needed to treat illness due to viral infection, but leading candidates are not available at this time. Drugs are also needed to prevent or treat radiation illness. Although no candidates are available for advanced development today, several leading candidates may become available for advanced development in the next few years. The MITS-JPMO is monitoring the technology base efforts at the Armed Forces Radiobiology Research Institute and is actively planning for the transition of candidate products.

Products Available for Defense Against Chemical Warfare Nerve Agents

Several drugs are currently fielded to protect warfighters against chemical warfare nerve agents. All products fielded prior to 2003 were the result of USAMRMC technology base and advanced development programs. Although the MITS-JPMO has assumed responsibility for advanced development of medical chemical countermeasures, the USAMRMC lab system still serves as its primary technology base. The MITS-JPMO maintains life cycle responsibility of these drugs to ensure that the products remain available to the DoD. One such drug, the Nerve Agent Antidote Kit (MARK I) was fielding in the early 1980s and contains atropine and 2-pralidoxime chloride

(2-PAM) in separate autoinjectors. While the MARK I is still in the logistics system, it is being phased out and replaced with the Antidote Treatment - Nerve Agent Autoinjector (ATNAA), which was approved by the FDA in January 2002. The ATNAA is a 2-chambered autoinjector that delivers both atropine and 2-PAM through a single needle. This reduces the number of injections required to protect warfighters against nerve agents. The ATNAA is also less expensive, smaller, easier to use and delivers the antidotes faster than the MARK I. Both the MARK I and the ATNAA can be administered by the warfighter or by his/her buddy at the onset of signs or symptoms of nerve agent poisoning. These include the constriction of the pupils, over production of saliva, runny nose, tearing from the eyes, sweating and muscle twitching. If these symptoms occur and treatment is delayed, the victim will progressively get worse and become unconscious. Muscle twitching will continue until the muscles become fatigued, breathing stops and the victim dies. The drugs in the MARK I or ATNAA relieve the symptoms and prevent or reduce muscle fatigue.

The FDA approved the Medical Aerosolized Nerve Agent Antidote (MANAA) in September 1990 for the treatment of mild to moderate nerve agent induced secretions and muscle twitches. The MANAA is an aerosol inhalant device (like those used by asthma patients) containing atropine and is used primarily in medical treatment facilities under medical supervision. It is intended for use after administration of either a MARK I or ATNAA and after the victim has been decontaminated and evacuated to a clean environment where there is no need for masks and protective suits. The victim should be conscious, lucid, and breathing spontaneously when the MANAA is used.

The FDA approved the Convulsant Antidote Nerve Agent (CANA) in December 1990 to prevent or reduce the seizures that often accompany nerve agent poisoning. The CANA consists of an anticonvulsant drug in an autoinjector that is carried by the warfighter. This drug is designed to protect the brain from the effects of nerve agent poisoning. When a person becomes a nerve agent casualty, his or her buddy administers the drug.

The FDA approved the Soman Nerve Agent Pretreatment Pyridostigmine (SNAPP) in January 2003 as a pretreatment for Soman nerve agent poisoning only. SNAPP is a tablet containing pyridostigmine bromide that is self administered every eight hours. SNAPP protects a critical enzyme that is involved in nerve signal transmission from inhibition by Soman. SNAPP is effective only when used in conjunction with either the MARK I or the ATNAA.

The Skin Exposure Reduction Paste Against Chemical Warfare Agents (SERPACWA) is a skin barrier cream. When applied on the skin it provides protection against both nerve and blister agents for a minimum of eight hours. It is applied to skin areas that underlie seams in the Mission Oriented Protective Posture (MOPP) such as the neck, wrists, ankles, waist, armpits and groin, thereby increasing the effectiveness of MOPP. The FDA initially approved the SERPACWA in February 2000 to enhance protection against chemical warfare agents when used in conjunction with MOPP. The original manufacturing scale was too small to meet DoD requirements so the manufacturing line had to be modified. The FDA approved the larger scale manufacturing process in February 2003. SERPACWA was fielded during Operation Iraqi Freedom under an Urgent Needs Statement. SERPACWA is chemically inert and does not interfere with chemical agent detection devices or other military equipment.

Products Under Development

Even though several products are fielded to protect warfighters against chemical warfare nerve agents, not all requirements have been met. In some cases new and improved drugs are required to replace the current drugs. In other cases, the indications of current drugs need to be broadened.

The Improved Nerve Agent Treatment System (INATS) is being developed as an improved treatment against the devastating effects of nerve agent poisoning. INATS will include a new oxime to replace 2-PAM in the ATNAA and new indications for SNAPP. The goal for the new system will be to provide greater protection against a broader spectrum of nerve agents.

The Advanced Anticonvulsant System (AAS) is being developed as a replacement for the CANA. The AAS is envisioned to prevent or terminate nerve agent induced seizures quicker than the CANA, thereby providing better protection to affected individuals. The AAS will be used in conjunction with the ATNAA. The bioscavanger is being developed as a drug to prevent illness caused by nerve agents. The bioscavanger is a natural human enzyme that binds to nerve agents preventing their action on the nervous system. Although the program is still in its infancy, the bioscavanger has the potential to protect individuals against battlefield levels of nerve agent without the use of MOPP.

The threat of chemical and biologic agent use on the battlefield or by terrorists is increasing. The requirement for current and future countermeasures is real and anticipated to increase. The MITS - JPMO is working to ensure that our Soldiers, Sailors, Airmen, and Marines have the best medical protection available to counter these threats.

"The requirement for current and future countermeasures is real and anticipated to increase."

Related Articles:
Critical Reagents Program (pg. 16);
JBAIDS (pg. 18)

The Critical Reagents Program (CRP) is responsible for the validation and production of all biological detection assays used by the U.S. military. To accomplish its mission, the CRP works closely with biodefense scientists at several Department of Defense (DoD) research laboratories to include the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the Naval Medical Research Center (NMRC), Dugway Proving Ground (DPG), the Research Development and Engineering Command (RDECOM), the Armed Forces Institute of Pathology (AFIP), and the Air Force Institute of Occupational Health (AFIOH). These ties facilitate the effective transition of new detection assays and improved technologies to protect the warfighter.

Lateral flow Hand Held Assays (HHA), which function very similar to pregnancy strips for detecting Biological Warfare Agents, make up the most recognized product line offered by the CRP. HHAs are used in autonomous biodefense systems such as the Joint Biological Point Detection System, and Portal Shield, or can be used manually as part of the DoD Biological Sampling Kits (NSN 6665-01-494-8725 and 6665-01-497-7811). Transitioned from the NMRC in 1999, HHAs were the first products offered by the CRP. In 2003, the CRP produced 8.8 million test strips that target 14 different biological agents. The popularity of the HHAs can be attributed to the fact that they are inexpensive ($5 each), easy to use, and provide a result in 15 minutes.

Introduced in 2000, Electrochemoluminescence (ECL)

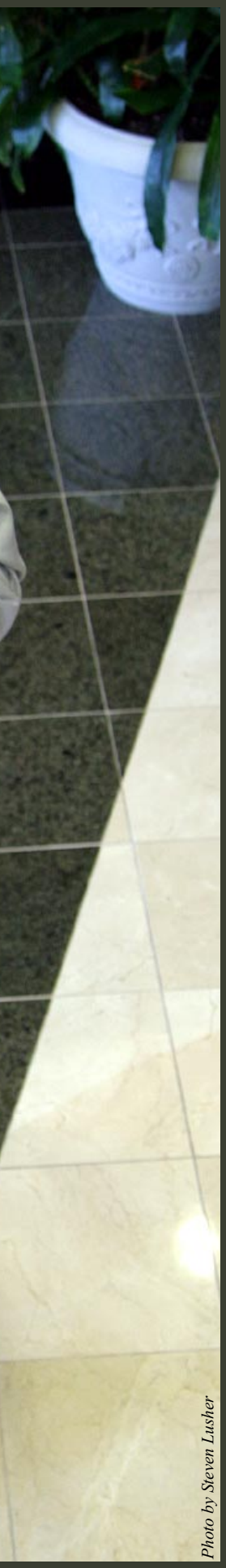


Photo by Steven Lusher

The Critical Reagents Program: Then and Now

By Dr. Peter Emanuel, Heidi Johnston, Lisa Mobley, Jennifer McLaughlin, Tricia Wilson, and Mike Mazza

immunoassays quickly became popular for their sensitivity and ability to detect targets in a variety of sample matrices. Initially developed by scientists at RDECOM, USAMRIID accelerated use of ECL assays in the aftermath of September 11, 2001. The freeze-dried single use assays, which only require the addition of the sample to be tested, come with positive control tubes. In 2005, we will see the introduction of the new M1-M (for militarized) analyzer platform. The toaster-sized M1-M unit is rugged, portable and can run up to 96 samples.

Freeze dried polymerase chain reaction (PCR) assays are now available for 10 threat targets. Unlike the HHA and the ECL assays, which detect proteins on the surface of the threat agent, the PCR assays detect threat agent gene sequences. The PCR assays can be used on the Applied Biosystems 7900/7000, Idaho Technologies R.A.P.I.D. thermocyclers, or the enhanced military version of the Idaho Technologies unit, the Joint Biological Agent Identification and Diagnostic System. Two different PCR assays are available for each biothreat agent, each assay targeting a different gene in the threat agent for greater specific detection. Because the PCR assays are more sensitive and more specific than the HHA or ECL assays, the PCR assays can be used to confirm tests results from the other assays.

To accomplish the CRP's mission, the program maintains several specialized repositories throughout the nation. These repositories develop and maintain standardized materials that contribute to producing the best possible CRP end products. The Critical Reagents Genomics Repository is located at the AFIP in Washington D.C. This site is responsible for producing and storing high quality DNA and RNA biological threat reference material that is available to the biodefense community in the form of standard panels. Dugway Proving Ground scientists manage the Critical Reagents Antigen Repository to produce and store panels of select agents that are used for detection systems testing and evaluation. Both the Genomics and Antigen Repositories produce reference materials from identical cell lines obtained from the DoD Unified Culture Collection (UCC). The DoD UCC is an extensive collection of cell lines whose lineages are well documented and have been confirmed to be free of contamination. USAMRIID curates the UCC and provides matched sets of cells to each participating CRP lab.

The DoD UCC is part of a larger Quality Management System (QMS) initiated by the CRP in 2003 that seeks to standardize how assays are documented and validated. The CRP QMS works with all Government laboratories, commercial manufacturing sites, and Conformance Test Laboratories (CTL). Each product has a dedicated Conformance Test Laboratory and a formal Conformance Test Plan (CTP) that documents how each and every production lot shipped from a manufacturer to the CRP will be tested. If a particular product fails to perform according to predefined standards established in the CTP, it is rejected and sent back to the manufacture.

The CRP has undertaken many changes in the past three years. One of the most ambitious changes is the antibody expansion program. Today, the Critical Reagent Antibody Repository located in Edgewood, MD, houses the world's largest collection of monoclonal and polyclonal antibodies directed against biothreat agents. However, with increased demand for CRP immunoassays and the need to target a greater variety of threats, the program is looking to the future. A DoD consortium was formed between the CRP, NMRC, USAMRIID and RDECOM to produce test and store a wider variety of antibodies.

Navy, Army, and Air Force scientists work closely to produce the highest affinity antibodies for the warfighter and coordinate their respective research and development efforts to develop the next generation of immunoassays. Integrated Product Teams meet regularly to discuss strategies and include not only DoD scientists but can include representatives from the Defense Threat Reduction Agency and the Joint Requirements Office. Better communication is allowing more opportunities to leverage ongoing efforts between multiple laboratories and has allowed the CRP to speed the transition of new detection assays.

The last three years has presented the biodefense community with many new challenges. The CRP, and the hundreds of dedicated scientists who work with the program, are rising to meet the need for the best biological assays for today and tomorrow.

Related Article: JBAIDS (pg. 18)

Dr. Peter Emanuel, JPEO-CBD CRP, displays a hand-held-assay, one of the items used to detect Anthrax and other biological agents.

The Joint Biological Agent Identification and Diagnostic System (JBAIDS)

The Future is Now

By Maj. Scott Wilson and Ms. Donna Boston

Photo by Steven Lusher

Front row, left to right: Pat Howard, Donna Boston (System Manager), Christie Carbaugh, Hal Stein. Back row, left to right: Pat Craig, Jim Karaszkiewicz, Lt. Col. Keith Vesely, Rick Bowlby.

It is busy in the local military emergency room on a Friday night, as usual. A Soldier comes in through the sliding doors, helped by an anxious family member. The patient is visibly ill, and upon examination is suffering from fever, muscle weakness, back pain and basic "flu like" symptoms. Further examination reveals a rash breaking out all over the body. Allergic reaction? Chicken-pox? Something else? Specimens are sent to the laboratory and in less than one hour the microbiology laboratory reports the patient has smallpox. The emergency room immediately isolates the patient and begins notification of a smallpox case to the chain of command.

The above scenario is not far fetched. The Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD), through the Medical Identification and Treatment Systems (MITS) of the Chemical Biological Medical Systems Joint Project Management Office, will soon be fielding the Joint Biological Agent Identification and Diagnostic System (JBAIDS). JBAIDS is a portable, modifiable system capable of simultaneous, reliable identification of multiple Biological Warfare (BW) agents and infectious disease agents. Medical personnel will use JBAIDS to quickly identify exposure to or infection by biological agents at multiple levels of health service support; from deployed front line areas to fixed-site medical centers within the United States. JBAIDS deployment includes mobile hospitals, fixed hospitals, hospital ships, and with preventive medicine units. Its use will be in routine medical support as well as contingency, humanitarian and homeland security missions.

Lessons Learned from Operation Desert Storm revealed the need for BW agent field detectors and in the intervening years materiel solutions were fielded to fill in the capability gaps. But the medical personnel identified a deficiency: the need for a portable, field ready diagnostic device to enable health care providers to quickly identify disease-causing biological agents from patient specimens. The idea for JBAIDS was first proposed as a Common Diagnostic System and research began into the feasibility of developing such a system.

The Anthrax attack letters within the U.S. mail system prompted the Department of Defense (DoD) to move forward on the concept to purchase and field medical BW agent identification equipment for installation and naval fleet medical defense. But there wasn't a common, standardized "workhorse system" with common support equipment, extensively validated diagnostic assays, common protocols or test methods, and training. Because this system would be used with human patient samples in a medical laboratory, and the results of its tests will be used by physicians to prescribe treatments, the U.S. Food and Drug Administration (FDA) would also have to clear the system for use as a diagnostic device.

Enter JBAIDS. This unique program combines a streamlined acquisition process with an evolutionary spiral development strategy in several stages, or blocks. This process provides a template for testing, evaluating and selecting the right device against established end user requirements. This means that representatives from all Services within the DoD as well as other Federal Agencies (such as Health and Human Services, Centers for Disease Control and Prevention, Department of Energy, Environmental Protection Agency) and the North Atlantic Treaty Organization (NATO) all gave input through participation on Integrated Product Teams (IPTs). The end result of the inputs is the Joint Operational Requirements Document (JORD).

The JBAIDS JORD describes the program as being delivered in three increments or blocks. Each block will build upon the capabilities of the previous block until the ultimate end product is obtained in Block III. JBAIDS Block I will be fielded in late 2005 with the capability to identify 10 different BW agents in 40 minutes or less within very stringent limits of specificity and sensitivity (low false positive and low false negative rates). It will meet other JORD specifications that make it ruggedized for field use, portable (weighing less than 40 pounds), and operable in extreme environmental conditions. The JBAIDS acquisition strategy calls for providing the right capability to support health protection of the force in the shortest period of time while reducing cost, meeting performance and maintaining schedule. *Pictured below is JBAIDS.*

"JBAIDS Block III is truly revolutionary in idea and design."

Official Army Photo

JBAIDS is a portable, modifiable system capable of simultaneous, reliable identification of multiple Biological Warfare (BW) agents and infectious disease agents.

Official Army Photo

With the addition of JBAIDS in field and fleet laboratories, and in hospitals and homeland installations, rapid confirmation of biological warfare agents and pathogens can lead to equally rapid treatment, prevention, and mission sustainment.

Finding the Future

The JBAIDS program management team conducted a Market Survey to find commercial companies with mature technology that would meet the specifications for JBAIDS Block I as listed in the JORD. This approach for finding Commercial Off The Shelf (COTS) solutions reduces overall cost of development, shortens the schedule of development to fielding and through competition increases the performance of the technology. Once the Market Survey was completed, a four-phase strategy was used to select the winning vendor, highlighted by a competitive "Fly Off," held at the Life Sciences Test Facility (LSTF) at Dugway Proving Ground (DPG), Utah. There, all vendors that had responded to the solicitation and passed certain criteria brought their systems to compete against one another.

This "Fly Off" was the first of its kind within the DoD medical community. Over a three week period each tested system had to meet specific "pass/fail" criteria such as agent identification performance, sample throughput, system weight, and set up time. On site evaluation of each system was accomplished using input from DoD scientists, engineers, logisticians, military end user representatives and operators. In the end, a formal Source Selection Evaluation Board staffed by representatives from across the DoD determined the winning vendor. The prime development contract for JBAIDS was awarded to Idaho Technology, Incorporated (ITI) in September 2003.

Bringing the Future to the Lab Now

The execution of the four-phase approach above was a short 15 months. The development time after contract award will be just 24 months until the first JBAIDS units are fielded. This is a remarkable 36-48 months shorter than the average development cycle for a DoD product. This ambitious approach encouraged full and open competition as a means to obtain mature COTS technology that could be modified to meet DoD needs.

JBAIDS Block I is currently scheduled to begin fielding in FY05, providing a capability to identify bacterial and viral biological agents within 40 minutes after specimen processing and preparation. This is accomplished using the polymerase chain reaction (PCR) technique, which identifies genetic material (Deoxyribonucleic Acid or DNA) in a sample. This is a vast improvement over traditional microbiology methods that take from 24-48 hours to several days to get results. Furthermore, the system is going to be fielded as a total system package including the analytical device within a hardened case, all of the assays needed to identify specific agents, equipment needed to conduct sample preparation and processing, and technical manuals. This means that receiving units or laboratories can begin to use the entire system immediately upon receipt, an important feature during increased tempo of operations.

JBAIDS Block II will add to the features of Block I the capability to identify biological toxins from patient or environmental samples. This will greatly enhance current medical laboratory capabilities since such samples are usually sent out to reference laboratories for toxin identification. Identification of toxins within the local laboratory will result in significant reduction in turnaround time and costs.

JBAIDS Block III is truly revolutionary in idea and design. It will be a lightweight, hand-held device with automatic sample processing, and will be capable of identifying 50 biological agents (bacterial, viral and toxin) within 15 minutes. Picture a Star Trek "Tricorder!"

The laboratory of the future as envisioned in movies and television is closer than many people think. Patented technologies to make diagnostic and detection devices smaller are already in use (such as glucose monitors, and hand held assays), while others are in research and development. With the addition of JBAIDS in field and fleet laboratories, and in hospitals and homeland installations, rapid confirmation of biological warfare agents and pathogens can lead to equally rapid treatment, prevention, and mission sustainment. The future really is now!

World Wide Chemical Conference AUSA Sea Air & Space APBI

Dr. Dave Edman, Bobbie Kirby, and Michael Mazza

Photo by Elizabeth Sass

Air Force Association Modern Day Marine U.S. Coast Guard U.S. SOCOM

Dr. David Edman with CBMS demonstrates the JBAIDS capabilities at the Medical AUSA. Each display highlights products of the seven Joint Project Managers.

2004: Upcoming Displays

Acquisition Senior Leaders	Aug 9-13
Air Force Association	Sep 11-15
Modern Day Marine	Sep 15-16
World Wide Chemical Conference	Oct 12-15
Conference on Science & Technology for Chemical and Biological Information Systems	Oct 18-21
Association of the United States Army	Oct 25-27
United States Special Operations Command	Dec 13-16

The JPM Information Systems CBRN Data Initiative

By Capt. Tom O'Keefe, USN

Introduction As we were establishing the infrastructure for the Joint Program Manager, Information Systems (JPM IS) we made a calculated decision to establish a comprehensive data initiative to explore a variety of critical questions that we recognized would impact on our Joint Warning and Reporting Network (JWARN), Joint Effects Model (JEM), and Joint Operational Effects Federation (JOEF) Programs. Many of these questions pertain to data interoperability.

Data interoperability has made its way to the forefront of the battle to improve the interoperability of Department of Defense (DoD) systems such as JWARN, JEM, and JOEF. For many years, the primary focus of the DoD interoperability efforts, as described in the Joint Technical Architecture (JTA) and the Common Operating Environment (COE) has been application interoperability. The latest version of the JTA (Version 6) clearly shifts the focus to data interoperability. Likewise, the latest version of the COE (4.7), which is a stepping-stone to the emerging Net-Centric Enterprise Services (NCES), includes new mandates with respect to data interoperability. The use of common data is critical to the success of the net-centric environment described in Joint Vision (JV) 2010 and JV 2020.

The Mission The Chemical-Biological-Radiological-Nuclear (CBRN) Data Initiative is a joint project within the Joint CBRN Defense Program. The mission of the Data Initiative is to promote the interoperability and reuse of CBRN Data across the JWARN, JEM, JOEF programs (as well as IJWARN/CBRN IS) and other CBRN programs.

The primary goal is to eliminate interoperability failures by mapping current and legacy CBRN data to a common reference schema. The use of a data schema promotes data reuse and standardization. Additionally, this initiative will look at issues of authoritative data sources, and data validation, verification, and certification. This directly supports the overall mission of the CBRN IS to provide valid, useful data on time to the warfighter.

The Method This mission will be achieved by developing a CBRN Data Model and related CBRN eXtensible Markup Language (XML) Schema for use by the Programs and the CBRN Community of Interest (COI), as well as by defining and implementing Common Semantics and Syntax (CSS) with respect to CBRN data. The Data Initiative will also define the data certification process and identify sources of authoritative CBRN data.

The CBRN Data Model uses the IDEF1X data modeling method and format, as specified in the JTA. Further, to ensure commonality with joint and coalition C4ISR systems, the data schema begins with a subset of the NATO Command and Control Information Exchange Data Model (C2IEDM), adds in those data elements needed to fully describe CBRN information, and relates that information to the existing C4 data elements resident in the current version of the C2IEDM. As the project progresses, the data team is making recommendations to the C2IEDM developers for expansion of that model to include the CBRN data. This will result in a common data schema that can be used by all CBRN applications that need

to interface with joint and coalition C4 systems, including simulation systems. In fact, one of the features of the CBRN Data Model will be links to the equations used by CBRN simulations. This will give users visibility into the underlying physics behind simulations such as the HPAC (Hazard Prediction and Assessment Capability) model.

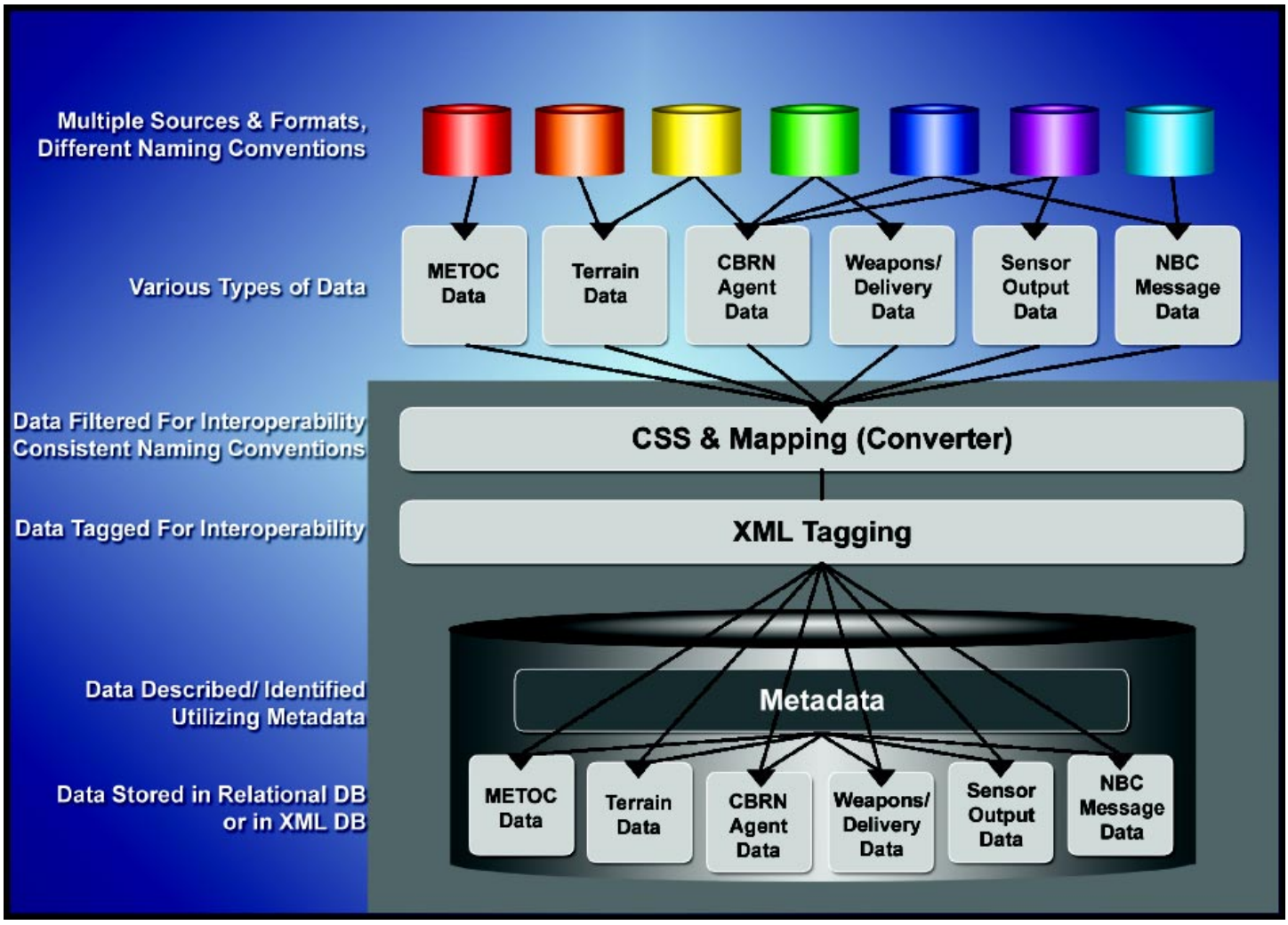
The use of XML is mandated (by the JTA) for data interchange. Development of a CSS will be the foundation of the free exchange of CBRN data via an XML schema. The first step, that of creating a CBRN Community-of-Interest (COI) XML Namespace Registry, has been accomplished.

Semantics is the study of meanings and accepted definitions. The same word may have multiple meanings. The same meaning may be conveyed with different words. Syntax may refer to either substantive/domain syntax or to technical syntax. Substantive syntax is the way in which linguistic elements (words) are put together to form constituents (phrases or clauses). Technical syntax is the manner in which data is structured and defined, such as with a data model.

For the CBRN community, the Data Initiative is creating a typological structure (substantive syntax) of CBRN operations/phenomena that includes CBRN-related terms and their definitions (semantics) formatted in a logical manner and in a relational way (technical syntax). A CSS for CBRN will enhance interoperability and reuse of CBRN data. It will also serve as a metadata filter to enhance common reference terms. The IDEF1X data schema (technical syntax) will facilitate data exchange using standard, well-defined, established data formats, thus ensuring the free flow of data from the various CBRN programs. It also lays the foundation for the creation of XML tags and schemas and assists in data quality checks for syntactic and logical consistencies.

There are many sources and types of data used for CBRN applications - including weather (METOC - meteorological and oceanographic) data, terrain data, sensor feeds, medical effects data, consequence management (CM) data, logistics data, resource data, NBC messages, and Modeling and Simulation (M&S) data. The schematic below gives a conceptual view of how those data repositories will be mapped to a common semantics and syntax (CSS) using the IDEF1X data schema, then tagged using XML to create new standardized data repositories that can be used for all CBRN applications. The metadata layer helps in the search for that data by users and potential users.

Progress to date has been encouraging. The Programs within JPM IS, including JWARN, JEM, and JOEF, are already benefiting from the data model and schema. North Atlantic Treaty Organization (NATO) has requested the use of CBRN Data Model by the ATP-45 Panel, Sub-committee 6 (NBC Communication and Information Systems and Warning & Reporting) in their review of NATO NBC Systems interoperability.



Human Testing of Counter-Measures for Biological Warfare Agents

By Sandra Geroux, Regulatory Affairs Analyst, Camber Corporation

Photo by Elizabeth Sass

Sgt. Marilyn Cortina demonstrates giving an injection to Spec. Goldie Mouton. Both service members are assigned to the U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD.

What is human testing and why is it so important? For the protection of the general public and members of the Armed Forces, the U.S. Food and Drug Administration (FDA) requires demonstration of safety and effectiveness in adequate, well-controlled studies. Clinical research studies are an integral part of new product discovery and development, and are required by the FDA before a new drug or biologic can be licensed (marketed).

Before human testing of a new drug or vaccine, researchers (called sponsors) must conduct extensive pre-clinical (animal) or laboratory testing. This research typically involves years of experimentation. If the pre-clinical work is successful, an Investigational New Drug Application (IND) is submitted to the FDA justifying the need for continued testing of the new product in humans. The IND application provides a clinical study plan called a clinical protocol. The clinical protocol is a written plan specifying what study procedures/tests will be done, by whom, and why. After the IND application is filed with the FDA, sponsors may begin clinical testing to study the safety and efficacy of the new product in human volunteers. A new product could be a drug, medical device, or a biologic such as a vaccine, blood product, or gene therapy. Some clinical studies are conducted to develop better ways of administration of already approved products or for new uses (indications) for existing products.

People participate in clinical research for a variety of reasons. They gain access to promising new products long before they are approved for marketing, and receive excellent care from qualified health care professionals (called investigators). This care may be free in accordance with the conditions of the clinical study protocol. They may also receive nominal monetary compensation for participation.
The volunteers' rights and safety are pro-

A placebo is an inert replacement for the drug or vaccine being tested. It looks like and is administered just like the test item but has no medical effect.

tected in two important ways. First, the investigator must obtain approval by an Institutional Review Board (IRB) to conduct a clinical study. The IRB reviews and approves the clinical protocol submitted by the investigator to ensure that the volunteer's rights are protected, and that the study does not result in undue risk to the volunteer. Second anyone who volunteers to participate in a clinical study must sign an informed consent (also approved by the IRB). The informed consent provides detailed information to the volunteers about the nature of the clinical trial, the risks involved, and possible outcome of the study for the participant.

Clinical studies are conducted at qualified facilities, such as hospitals, research centers, and/or clinics, and are conducted in a series of steps called phases.

Phase I studies are the first step in testing an investigational new product in healthy normal subjects and are primarily for the purpose of assessing the safety of the drug or vaccine. This initial phase of testing in humans is done in a small number of volunteers, usually less than 100. These studies are designed to determine what happens to the new product in the human body; how it is absorbed, distributed, metabolized, and excreted. Phase I studies investigate side effects, if any, that occur as dose levels are increased. This initial phase of testing takes several weeks to several months. Subjects are divided into groups or cohorts. Each group is treated with an increased dose of the investigational drug or vaccine. The highest dose administered, with an acceptable level of side effects, is then developed for further testing.

Phase II clinical studies are performed once the product has been shown to be safe. The new product is then tested for efficacy and additional safety. This second phase of testing may last from several months to several years and involves up to several hundreds of patients (volunteers) with the disease or condition that the new product may benefit. These studies are generally well-controlled, randomized (each patient is assigned to a group by random selection) and "blinded," (neither the investigator nor the patient know who receives what treatment). Patients are randomly assigned into either an investigational treatment group, a group treated with a product of known efficacy, or a placebo group. A placebo is an inert replacement for the drug or vaccine being tested. It looks like and is administered just like the test item but has no medical effect. Its purpose is to account for the fact that some people report feeling better when they think they have received a drug even when what they received had no medical effect on them. Side effects and risks associated with the investigational product are closely observed as further monitoring of safety.

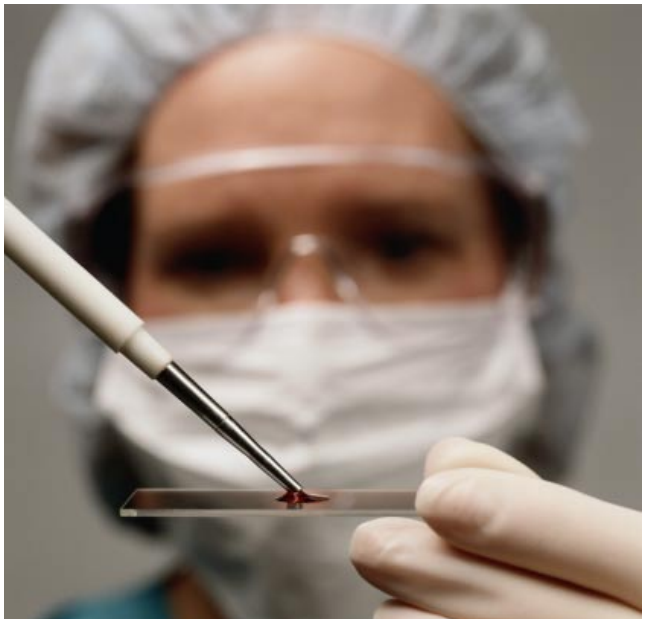
Phase III clinical studies test the new product in several hundred to several thousand patients and can last for several years. This large scale testing provides the sponsor with a more thorough understanding of the drug's effectiveness, benefits, and the range of possible adverse reactions required for labeling. Phase III studies are generally well-controlled, randomized and blinded studies. Once the Phase III studies demonstrate acceptable safety and efficacy, the sponsor can submit a New Drug Application (NDA; for pharmaceuticals) or a Biological License Application (BLA; for vaccines) to the FDA for possible approval of the new product. The NDA/BLA includes all data from the testing and manufacturing of the product for FDA safety and efficacy review. It generally takes the FDA a year to review and approve an NDA/BLA.

Once a new product is approved by the FDA for marketing, a sponsor may continue to study the product, or the FDA may require additional studies from the sponsor, to compare it with other approved products and to monitor the new product's long term effectiveness and safety. These are known as Post-Marketing studies (late Phase III/Phase IV studies).

Clinical research is the most expensive and time consuming part of product development, but without clinical research no new or innovative products would reach the market.

The discussion above on clinical trials is the normal way that drugs and vaccines are tested to meet FDA requirements for safety and effectiveness against disease. However, when the "disease" is a chemical or biological weapon, this system must be modified.

Related article: The Animal Rule (pg. 11)



Testing provides an understanding of drug's effectiveness, benefits, and a possibility for adverse reactions required for labeling.

A Time for Change . . .

New 'Smart Marker' Technology for the Warfighter

Maj. Bruce Archambault, Mr. Mike Cress

Throughout the 1980's, the Chemical Corps sought a Nuclear, Biological and Chemical (NBC) reconnaissance capability that would prevent the possibility of an unwarned encounter with contaminated terrain. With the type classification of the German Tpz-1 Fuchs vehicle as the standard NBC reconnaissance asset, the U.S. Army gained its first capability of rapidly detecting terrain contaminated with chemical agents. The U.S. variant was designated the M93 Fox NBC Reconnaissance System. One of the key features of the system is a marker set which consists of a weighted base, a wire mast, and pennants for each class of hazard (Nuclear, Biological or Chemical). Enough components to assemble 175 markers are stored inside the crew compartment of the vehicle. The current version of the vehicle, the M93A1 has a marker chute that allows assembled markers to be dropped outside without compromising the collective protection of the vehicle.

Starting with the first Great War (1914-1917) various methods of marking contaminated areas have been used. All have shared the same goal of preventing the unwarned encounter of a chemically contaminated area. The protocol for annotation of the pennant or marker has remained relatively unchanged over the years. When emplaced, the unit date time group and hazard type is written on the marker, typically using a grease pencil. The identification of these markers is a common task at skill level one (031-503-1019-React to a Chemical or Biological Hazard Attack). The adequacy of the Fox marker system was an issue during the field-testing of the system prior to type classification. With the limited numbers of markers on board, it was clear that placing them around typical contaminated areas would quickly consume the entire basic load of markers. Soldiers also raised issues with the visibility of the markers during periods of darkness and the limited amount of information available at the marker. Following type classification of the Fox, units in the field began to report difficulty in seeing the marker and there was a tendency for the markers to tip over in rough terrain or windy conditions.

In 1997 the U. S. Army Chemical School Directorate of Combat Developments (DCD) drafted a concept for the digital marking of contaminated areas. A Concept Evaluation Plan (CEP), entitled 'Smart Marker' was proposed. A limited scale in-house project to demonstrate a long duration infrared (IR) beacon was conducted at Fort Leonard Wood in 1998. The goal of the project was to determine if a small, thumbnail sized IR beacon could be used to improve the visibility of a Fox NBC marker. The project was a success with the beacon working for 87 days on one AAA battery.

The success of the beacon project prompted an investigation into how data might be added to an NBC marker that potentially could be included in a product improvement of the marking system. These studies shared a common constraint, whenever possible; use Commercial-off-the-Shelf (COTS) technology or components. In 2000, Fort Leonard Wood's Maneuver Support Battle Lab (MSBL) successfully investigated the concept of a Smart Marker through a Training and Doctrine Command (TRADOC) CEP using only COTS technologies.

The approach taken by Col. Donald Burnett, the Joint Program Manager for NBC Contamination Avoidance (JPM NBC CA) and the Chemical School's Maneuver Support Center (MANSCEN) DCD this spring was to design a marker for today, using the requirements for the Future Combat System (FCS) of tomorrow, while employing existing COTS technology or components.

The FCS Operational Requirements Document (ORD) calls for a visibility requirement of 200 meters during day, 500 meters at night and an IR night visibility of 200 meters. Data transmission requirements state a power supply capable of 24/72 hrs. threshold/objective (T/O) with a position location of plus or minus 10 meters and a radio frequency (RF) capability of 100/500 meters T/O. The Fort Leonard Wood CEP proved these ORD requirements could be met with COTS technology and components.

The Smart Marker Program is a concerted effort between numerous organizations and includes JPM NBC CA Reconnaissance Vehicles and Battle Management Systems, Fort Leonard Wood's Chemical School DCD, Fort Monmouth's Communication and Electronics Command (CECOM), Edgewood's Advanced Design and Manufacturing (ADM) Team, and Fort Hood's Central Technical Support Facility.

The Smart Marker being developed by the JPM NBC CA is partitioned into two increments. The First Increment Smart Marker provides an improved visual capability and addresses the problems involved in detecting the markers through two improvements to existing markers. Improvement emphasis will focus on a COTS beacon or Light-Emitting Diode (LED) and an enhanced flag color which is compliant with the Illumination and Engineering Standards. Lessons learned from the DCD experiment demonstrated the marker's LED must have a dimpled, or diffused lens, which significantly improves the warfighter's ability to see

the light through the reflection and refraction of light as it passes through the lens. Edgewood's prototype shop is developing an injection molding process to mass-produce this dimpled lens.

One Increment I solution under consideration consists of a prepackaged, low cost "NBC Marker Enhancement Kit." The concept for the kit is a foil or zip lock type of packaging about one-half the size of a Meal, Ready-To-Eat that contains the three new improved flags, a one-time-use flasher which might clip to the NBC Marker, and a couple of plastic zip ties to attach flag & flasher to the marker staffs (flasher may be able to be reused).

The Second Increment Smart Marker provides for a data capability. Emphasis is on providing a COTS Global Positioning System (GPS) and early warning RF capability while employing real-time data tracking and battlefield marking capability. The technology is present; the challenge is engineering today's technology into some sort of a potted device at the base of the marker.

Both increments will require a re-computation of the NBC Contamination Marker basic load as each increment is completed and tested. The new Smart Markers will ultimately mean fewer markers and should result in a significant reduction in the weight of today's NBC Contamination Marker basic load.

Our research into the Smart Marker has uncovered the potential need for a fourth type of marker flag. Our lessons learned from Operation Enduring Freedom (OEF)/ Operation Iraqi Freedom (OIF) have shown in addition to the standard NBC contamination marking requirements present today, we should consider a fourth type of marker flag to identify Toxic Industrial Chemicals and Toxic Industrial Materiel (TICS/TIMS). MANSCEN DCD is reviewing this request for the implementation of a fourth flag.

Our preliminary market survey and investigation into COTS solutions is promising. We will test four different styles of enhanced markers later this spring and are on schedule to field the Increment I Marker enhancements by 4QFY04. The simple addition of different colored flags and a commercially available stick on beacon will make an immediate and dramatic difference in the ability to detect the marker during periods of limited visibility.

Leveraging available technology for Increment II will allow the standoff download of detailed hazard information via RF modem. Download will also be possible via IR and hardwire through a communications port. During the Smart Marker CEP, detailed hazard data was visible in the cab of a truck 300 meters before the marker was physically encountered. It may also be possible to leverage the same RF technology that is planned for use by today's Army logisticians to track Mobilization Readiness Exercise (MRE) movements in Theater.

Testing of the Increment I Marker will be straightforward and informal. Ideally we'd integrate our Increment I Markers into the Combat Training Center (CTC) rotations, where the critical observations first originated. However, the standard 30-day CTC rotation was replaced with MRE as units train and prepare for the largest rotation of troops since WW II in support of OIF II. By leveraging off of existing Military Occupational Specialties (MOS) L5 training at Fort Leonard Wood and Platoon lanes w/ III Corps units training for National Trailing Center (NTC) rotations this summer we will achieve the same level of user feedback.

While our efforts are only focused on the Fox Reconnaissance Vehicle NBC Contamination Markers, our work could be leveraged for numerous other applications within the Joint services such as minefield and hazards locations, targeting and traffic control warning and markings.

Photo by Elizabeth Sass

Anthrax Vaccine Adsorbed: Force Protection and Beyond...

By Ms. Lucy Gibson, Scientist, Camber Corporation

In September 2003, the Joint Vaccine Acquisition Program (JVAP) observed an important milestone in the Anthrax Vaccine Adsorbed (AVA) production program. BioPort Corporation, the only producer of U.S. Food and Drug Administration (FDA)-licensed Anthrax vaccine BioThraxTM, celebrated its five-year anniversary. After five years of operation, BioPort is completing deliveries on its first production contract with Department of Defense (DoD) and has begun to produce vaccine under a new, three-year, follow-on contract. Under this new contract, Anthrax vaccine will be made available, through an interagency agreement, to the Centers for Disease Control and Prevention's (CDC) Strategic National Stockpile of medicines and other critical supplies to be used in the event of a national public health emergency.

Photo by Elizabeth Sass

BioPort is completing deliveries on its first production contract with Department of Defense (DoD) and has begun to produce vaccine under a new, three-year, follow-on contract.

As the manufacturer of one of only two licensed biodefense vaccines, the other being the Smallpox vaccine DryVaxTM manufactured by Wyeth, BioPort has overcome unique scientific and regulatory obstacles to become a major contributor to the protection of the warfighter against the deadly threat of biological weapons.

Photo by Elizabeth Sass

Sgt. Richard Thompson, U.S. Army Medical Research Institute of Infectious Diseases, Fort Detrick, MD, prepares an innoculation.

BioPort Corporation was founded in 1998 to acquire the assets of the Michigan Biologic Products Institute from the Michigan Department of Public Health. The State of Michigan had stopped AVA production in January 1998 to focus on long-planned and much-needed renovations. BioPort continued with the renovations after purchase. In the mid-1990s, the FDA instituted new and more stringent regulations regarding manufacturing all biological products. Thus, when renovations were completed by BioPort, the new and more stringent regulations were applicable. It was under these conditions that

in 2002, BioPort received FDA approval to produce AVA in its newly renovated facility and the distribution of product resumed. In the two and a half years since restart of full production, BioPort has been able to make a number of improvements with the assistance of the DoD, particularly in the areas of risk mitigation and critical utilities upgrades. They have also achieved significant capacity increases by streamlining the existing manufacturing processes while continuing to meet contract delivery requirements.

To fully appreciate the role AVA plays in safeguarding against biological attack, one can reflect on the threat posed by weaponized Bacillus Anthracis, the causative agent of Anthrax disease. Anthrax is one of the easiest biological agents to produce and weaponize. In nature, it is a disease of wild and domestic animals and can be transmitted to humans through contact with animal hides, leather or hair products, or consumption of infected livestock. It has been used in biowarfare programs since the start of the 20th century; from the Germans in World War I, who used Anthrax to infect livestock, to the Japanese in World War II, the Soviets and Iraq. The recent Anthrax mail attacks of 2001 that killed five people and sickened 17 others were a grim reminder of the menace of bioterrorism poses not only to our military, but also to the civilian population at large. Infection by B. Anthracis Spores, like those milled into a fine powder in the 2001 attacks, can result in cutaneous lesions, gastrointestinal disease, or inhalational Anthrax, the most deadly form of disease. AVA is licensed to protect against all three types of Anthrax disease when used as prophylaxis in a pre-exposure setting. The 2002 Congressionally mandated report by the National Academy of Science's Institute of Medicine (IOM), "The Anthrax Vaccine. Is it safe? Does it work?", concluded that AVA is safe and effective. As indicated by results of human and animal studies, the independent committee found that AVA, as licensed, is an effective vaccine to protect humans against Anthrax, including inhalational Anthrax. The vaccine's mechanism of action should be effective against all known strains of B. Anthracis as well as any potentially genetically engineered strains.

The vaccine was originally approved by the FDA in 1970. Every lot is tested for potency, purity, safety and efficacy at BioPort and additional tests are performed at the FDA prior to release of any product. Like all other licensed vaccines, the FDA must approve each lot of AVA individually before it can be used. The dosing regimen consists of six injections, given subcutaneously, at zero, two, four weeks and six, twelve and eighteen months, followed by an annual booster. There has been discussion in the scientific community concerning whether this number of shots is necessary to elicit protection and if local reactions like redness and swelling at the injection site can be reduced by giving the vaccine by the intramuscular route. To answer these questions the CDC is conducting a large clinical trial to study the feasibility of a dose reduction and route change. An interim analysis of results will be released in Fall 2004 that may support the elimination of one dose. A long-term study will continue until 2007 to determine if the dose regimen can eventually be reduced to only three doses.

As the sole supplier of Anthrax vaccine to the DoD, BioPort has worked hard to successfully renovate, regain, and maintain FDA licensure of the AVA manufacturing facility that was operated by the State of Michigan. Since renovation of the plant and resumption of deliveries to DoD in January 2002, the partnership of BioPort and the JPEO-CBD has succeeded in meeting the requirements of the DoD while striving for continuous quality improvement and increased production rates. In the five years since BioPort purchased the Michigan plant, and program oversight responsibilities were assigned to Product Manager JVAP, an alliance has been forged to secure and sustain the commitment to force health protection and, in addition, to the defense of the nation through an agreement to provide millions of doses of AVA to the Strategic National Stockpile, managed by the CDC. The alliance that exists between DoD and BioPort is strengthened through their dedication and constant commitment to quality. The entire workforce displays a strong sense of teamwork and pride and this has been a motivator in their willingness to tackle adversity in order to contribute to the war against bioterrorism.

Photo by Elizabeth Sass

The 5th Joint Service Chemical and Biological Decontamination Conference

By Mr. Tommy Leung

Since 9/11, the world community has displayed an increased interest in Weapons of Mass Destruction. Chemical and biological defense is no longer limited to the battlefield during wartime. It now includes the homes and neighborhoods in which we live. The need for sharing information is important to tackle the complex issues of chemical biological defense. The Joint Service Chemical and Biological Decontamination Conference is a leading forum for sharing information within the chemical biological defense community.

From May 17 through May 20, 2004, the Joint Program Manager for Decontamination and the Defense Threat Reduction Agency hosted the 5th Joint Service Chemical and Biological Decontamination Conference, in Palm Harbor, Florida. The conference provided a forum for dialogue between civil and federal government, industry, academia, foreign representatives, and first responders on critical decontamination issues on the battlefield, at fixed sites, and in our communities. There were many new attendees this year, including representatives from the Department of Homeland Security and the emergency response community. Their objectives were to share information and more importantly to gain insight on one of the key elements of chemical biological defense-decontamination. The conference, consisting of three and a half days of presentations, workshops, discussions, and exhibits, focused on increasing global awareness of these critical issues and exploring leading edge solutions to the challenges.

In the past, decontamination meant removing or neutralizing chemical and biological hazards from warfighters so they can continue with their mission without degradation to combat effectiveness. Now, decontamination must include reducing civilian casualties and returning their lives to normal as quickly as possible. In the new age of terrorism, chemical and biological avoidance and protection may not always be possible for the masses, thus, decontamination is especially important in the reduction of casualties and panic in the event of a Weapons of Mass Destruction terrorist attack. It has become more imperative that the chemical-biological community works together, sharing information and leveraging each other's strengths to devise chemical biological solutions to both the warfighters and the civil support communities.

This year's Decontamination Conference brought in leading experts from academia to talk about the current and next generation solutions to chemical-biological contaminations. Dr. Vincent Fischetti, Rockefeller University, discussed one such innovation, describing the use of enzymes to break down protective coating of organisms such as Anthrax spores, causing it to explode from internal pressure. Some of the speakers included R. Stan Brown, Department of Chemistry, Queen's University, discussing "Metal Ion Catalyzed Alcoholysis Reactions as new Protocols for the Decomposition of Neutral Organophosphorus Esters;" Terrence Collins, Carnegie Mellon University, discussing "A Novel Catalytic Oxidative Decontamination System for Chemical and Biological Warfare Defense;" and Bill Nelson, University of Illinois-Urbana, discussing "Designer Ionic Liquids-Microemulsions for Decontamination."

Photo by Steven Lusher

The Joint Service effective defense policy mandates that U.S. Forces must be prepared to survive, fight and win in chemical biological contaminated environments.

The three centerpiece programs under the Joint Program Manager for Decontamination, the Joint Platform Interior Decontamination, the Joint Service Sensitive Equipment Decontamination, and the Joint Service Family Decontamination System, gave presentations on the unique challenges and solutions in meeting the warfighters' requirements. Bill Schlegel, the Joint Platform Interior Decontamination manager, discussed the challenges of vehicle interior decontamination while on the move. The Joint Service Sensitive Equipment Decontamination manager, Gyleen Fitzgerald, focused her presentation on the challenges and solutions of decontamination efficacy and material compatibility. While the Joint Service Family Decontamination System manager, Victor Murphy, spoke of the warfighters' field decontamination challenges. These programs represented the present and future of decontamination capabilities for the warfighters and the civilian community.

In addition to the Joint Program Manager for Decontamination programs, the Environmental Protection Agency presented lessons learned from the Anthrax decontamination effort at the Hart Senate Office. Many from the Department of Homeland Defense and the civil response community were especially interested to see how these lessons learned could be applied to their operations to improve their processes.

The industry contributed to the conference with displays of current decontamination products. Conference attendees were able to see and touch some of the products available from the industry for chemical-biological decontamination and to speak with industry representatives on challenges facing the industry. Some conference attendees were even able to try out a decontamination apparatus. The M100 Sorbent Decontamination System, a fielded Army and Marine Corps system, had a glovebox booth set up to allow conference attendees to simulate using the M100 Sorbent Decontamination System in a decontamination scenario. Many who used the simulation enjoyed the experience, as it provided perspective in the challenges of decontamination.

The 5th Joint Service Chemical and Biological Decontamination Conference was not only a forum for the exchange of ideas and information, but also a place for networking between people in the chemical-biological defense community who would not likely have met otherwise. The conference brought together people from around the world from different disciplines of study.

The conference hosted several casual events to allow attendees to become acquainted and build contacts that may open up new areas or create new partnership in our mission of chemical-biological defense. Events such as the afternoon socials provided a casual atmosphere, while events such as the basketball and golf tournaments facilitated team building in a friendly competitive environment.

The 5th Joint Service Chemical and Biological Decontamination Conference is no longer just a warfighters' event, but one for the entire world community in our fight against Weapons of Mass Destruction. Joint Program Manager for Decontamination hopes to continue growing the chemical-biological defense community, guiding it in its mission of chemical biological defense, using forums such as the Joint Service Chemical and Biological Decontamination Conference.

'The Reason for Our Success is Our People.'

Awards

Awardees

Order of the Dragon

Mr. Lee Anderson
Mr. Larry Bocknek
Mr. Douglas W. Bryce
Col. Neal Burnette
Cmdr. Charles H. Cutshall, Jr.
Mr. Stanley Enatsky
Ms. Lauren M. Ishmael
Dr. David Cullin
Ms. Elaine Neary

Special Recognition

Ms. Cherri Wright
Ms. Holly Tatem
Lt. Col. Dale Takenaka
Mr. Darrell McCarthy
Mr. Scott Paris
Ms. Brenda Besore
Ms. Delaine Richards
Maj. Gordon Graham
Ms. Nancy Mitarotonda
Maj. Paul Panozzo
Ms. Elaine Neary
Mr. Mark Myers
Ms. Angie Little











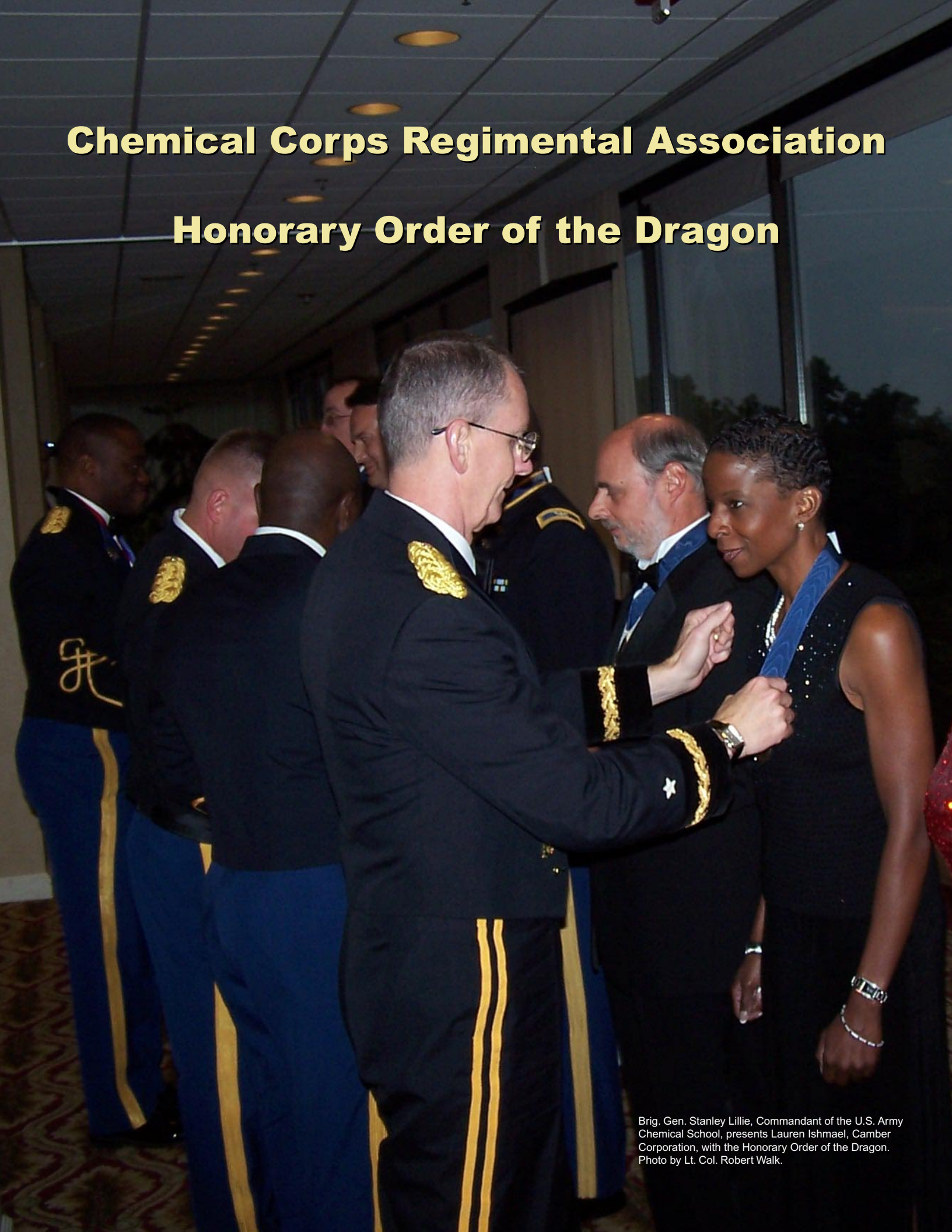


Photos by Elizabeth Sass and Steven Lusher

(Center Picture) Mrs. Nancy Mitarotonda retires after 37 years of loyal government service. Pictured with Brigadier General Stephen V. Reeves at a retirement ceremony held in her honor. She was presented with the flag that was flown over the White House in recognition of her dedication. Honored key speakers where Maj. Gen. John Doesberg, Commanding General RDECOM and Brig. Gen. (Ret.) Walter Busbee. (Special recognition awardees listed above).

Chemical Corps Regimental Association

Honorary Order of the Dragon



Brig. Gen. Stanley Lillie, Commandant of the U.S. Army Chemical School, presents Lauren Ishmael, Camber Corporation, with the Honorary Order of the Dragon. Photo by Lt. Col. Robert Walk.